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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,420	02/19/2004	Timothy G. Laske	P-10756.02	6294

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,420	LASKE ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2006 and 01 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 27 December 2006 with respect to claims 1–8 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Information Disclosure Statement

2. The information disclosure statement filed on 17 September 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because Applicant did not submit entry BF for consideration. It has been placed in the application file, but the information referred to herein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because a) reference character "2" (Figure 1) has been used to designate both right atrium and atrioventricular node; and b) reference characters "262" and "263" have both been used to designate anchoring tine. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement

Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. Claims 1–8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is "mapping locations" within the identified interventricular septal zone according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement, and selecting an electrode implant site from the "mapped locations" where a mapped location exhibits a ratio of P-wave amplitude that is less than approximately 0.5 and exhibits a pacing threshold is less than or equal to approximately 1.5 volts in combination with the other elements in the claim(s). Examiner is unable to locate disclosure in Applicant's written description that associates or correlates or shows a combination of the mapping/mapped criteria with that of a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement, and a mapped location exhibits a ratio of P-wave amplitude that is less than approximately 0.5 and exhibits a pacing threshold is less than or equal to approximately 1.5 volts.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1–8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the phrase "to a ratio of measured P-wave …and a pacing threshold measure" makes the claim incomplete for omitting essential steps. It is unclear if the method contains steps for measuring the ratio and for measuring the pacing threshold.

Claims 2–7 recite the limitation "the step of positioning an electrode." There is insufficient antecedent basis for this limitation in claims 2–7.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1–8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al., U.S. Patent 6,643,546 in view of Anderson et al., U.S. Patent 4,453,551.

10. Regarding claim 1, 3, 4, 5, 6 and 8, Mathis et al. disclose identifying a zone within an interventricular septal, which is in proximity to a bundle of His where pacing stimulation results in a rhythm breaking out at an intrinsic location (e.g., Figs. 9–19; ABSTRACT, lines 2–9 and 12–13; column 3, lines 10–14; column 7, lines 43–48 where it is noted that Applicant discloses that the bundle of His extends from the AV node within the fibrous tissue between the tricuspid and mitral valves, where the atrioventricular septum joins the interventricular septum, and into the interventricular septum (page 2, lines 14–17) and it is the Examiner's position that Figs. 9–11 show the bundle of His as disclosed in Applicant's written description);

mapping locations and positioning an electrode at different locations within the identified interventricular septal zone according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold, sensing a P-wave and an R-wave at each location and measuring P-wave and R-wave amplitudes and pacing at each location and measuring a pacing threshold (e.g., Figs. 3, 4 elements 36n and 42; column 1, lines 39–47; Fig. 23; column 3, lines 36–41 and 49–62; column 13, lines 65–67 column 14, lines 4–6 and 60; column 17, lines 25–26 and 31–55 where it is the Examiner's position that in the broadest reasonable interpretation, with P-waves and R-waves being present in the electrical signals as described in the cited section above and in an ECG as used, P-wave and R-wave amplitudes are sensed and measured and a P-wave to R-wave amplitude ratio is measured, and they have to present a ratio because by definition a ratio is relation in degree or number between two similar things. *Second College Edition The American Heritage Dictionary* Copyright © 1982);

selecting an electrode implant site from mapped locations (e.g., Fig. 23, elements 1, B, B1, B2, minimally); implanting an electrode at a selected implant site to deliver physiological pacing (e.g., column 3, lines 41–45; column 13, lines 29–30).

Mathis et al. do not disclose a ratio of P-wave amplitude to R-wave amplitude that is less than approximately 0.5. However, Anderson et al. disclose analyzing statistically the slopes of the ECG signal (e.g., column 4, lines 53–55) which, in the broadest reasonable interpretation and it is the Examiner's position, teaches a ratio of P-wave amplitude to R-wave amplitude because the slope (which is a ratio) of the entire ECG signal includes both the P- and R-waves amplitudes (see also, e.g., column 2, lines 49–51; column 5, lines 36–39) that is less than approximately 0.5 (e.g., column 5; lines 45–47; column 7; line 66–column 8, line 2) to yield the predictable results of effectively detecting and subsequently treating a heart condition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Mathis et al. to include a ratio of P-wave amplitude to R-wave amplitude that is less than approximately 0.5, as taught by Anderson et al. because it is an acceptable practice to apply a known technique to a known device ready for improvement to yield predictable results such as, in the instant case, effectively detecting and subsequently treating a heart condition. It is noted that, in the broadest reasonable interpretation, Anderson et al. teach mapping because mapping is the recording of the electrical activation sequence of the heart (*Advances in Catheter Ablation for the Treatment of Cardiac Arrhythmias*, Arnold J. Greenspon, March 4, 2000, IEEE).

Mathis et al. and Anderson et al. do not disclose a pacing threshold is less than or equal to approximately 1.5 volts. However, it is well known in the art to have a pacing threshold less

than or equal to approximately 1.5 volts to yield the predictable results of providing significant increase of measurement resolution and allowing high-resolution measurements without compromising patient safety and for safely and reliably pacing the heart.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Mathis et al. and Anderson et al. to include a pacing threshold is less than or equal to approximately 1.5 volts to yield the predictable results of providing significant increase of measurement resolution and allowing high-resolution measurements without compromising patient safety and for safely and reliably pacing the heart.

11. With respect to claim 2, Mathis et al. disclose positioning a pair of electrodes at different locations by varying an insertion depth (e.g., Fig. 10, elements E1 and E3 where the depth of insertion of E1 is lower in the interventricular septal zone than that of E3).

12. Regarding claim 7, Mathis et al. and Anderson et al. do not disclose inserting a single or pair of electrodes by advancing a single electrode or pair of electrodes epicardially. However, it is well known in the art to insert a single or pair of electrodes by advancing a single electrode or pair of electrodes epicardially to yield the predictable result of providing ease of recording an epicardial electrogram for optimum cardiac rhythm management signal acquisition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Mathis et al. and Anderson et al. to include inserting a single or pair of electrodes by advancing a single electrode or pair of electrodes epicardially because use of a known technique to improve similar devices in the same way to yield the predictable results of, in the instant case, providing ease of recording an

epicardial electrogram for optimum cardiac rhythm management signal acquisition, is an acceptable practice.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Daly et al., U.S. Patent 4,337,776 disclose a pacing threshold in the vicinity of 1.5 volts. MacDonald et al., U.S. Patent Application Publication 2002/0133199 disclose a typical voltage required to pace the heart is 1.5 volts. Ding et al., U.S. Patent Application 2003/0105492 discloses a single electrode or pair of electrodes epicardially.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. L. S./
Examiner, Art Unit 3762
February 13, 2008
/George R Evanisko/
Primary Examiner, Art Unit 3762